2. The method according to claim 1 wherein the antibody or antigen to anti-HIV is [can be] selected from the group consisting of anti-HIV (I or II), anti-anti-HIV, HIV antigens (I or II), recombinant HIV antigens, HIV aptamers, anti-Human IgG, IgA, IgD, IgE, or IgM.

3. The method according to claim 1 in which the buffer is [can] selected from the [following] group consisting of citrate, hepes, tris (trizma), taps, popso, tes, pipes, mopso, tricine, mops, mes, bicine, bes, caps, epps, dipso, ches, capso, ampso, aces, ada, bis-tris-propane, tapso, heppso, tea, amp, phosphate, phthalate, succinate, hydrochloric acid, sulfuric acid, nitric acid, acetic acid, sodium hydroxide, and potassium hydroxide.

4. The method according to claim 1 wherein the test sample is [can be] any biological fluid selected from the following group: urine, serum, whole blood, saliva, cerebral spinal fluid, gastric contents, and extracts of hair or sweat.

9. The method according to claim [1] 6 for determining the anti-HIV concentration of a test sample wherein the sample can be normalized comprising the steps of dividing the anti-HIV concentration by creatinine, cystatin C, or specific gravity concentration [can be used to normalize the sample for accurate determination of anti-HIV].

10. The method according to claim [9] 7 [wherein the calculation to normalize] for determining the anti-HIV concentration of a test sample wherein the sample can be normalized comprising the steps of [requires that it be] divid[ed]ing the anti-HIV concentration by the creatinine, cystatin C, or specific gravity concentration [of the same

test sample thereby yielding the anti-HIV to creatinine, cystatin C, or specific gravity ratio].

Comments on claims 9 and 10 in Response to the Examiner questions:

As described in detail and length in the specification pages 27, 28, and 34-36 the novel use of "creatinine or cystatin C excreted by a normal, healthy individual is relatively consistent from day to day", page 28, 1st paragraph of the specification. As known in the art and as stated in 'Tietz Textbook of Clinical Chemistry, 2nd Edition", 1994, W.B Saunders, page 1533, 2nd paragraph, "Because creatinine is endogenously produced and released into body fluids at a **constant rate** and its plasma levels maintained within narrow limits, its clearance may be measured as an indicator of GFR." (GFR, stands for glomerular filtration rate), therefore, the use of creatinine or other steady state markers are valid for consistent day to day measurement of urine concentration.

Specific gravity concentration is "A useful guide to the adequacy of the renal concentrating mechanism is measurement of urine specific gravity" as stated in the above reference page 1556, 3rd paragraph.

The Examiner asks:

a) What is the sample "normalized" to? Answer: The samples anti-HIV value is normalized to a specific value by dividing the anti-HIV value by the creatinine, cystatin, or specific gravity concentration of the test sample. See pages 35 and 36 of the specification for more detail.

b) Is there a specific concentration necessary for the samples before employing the test method? Answer: No. See pages 35 and 36 of the specification for more detail.

c) Is it possible to use these reagents or not? Answer: The term "reagents" not used in claim 9 or 10.

REMARKS - General

The applicant has rewritten the above claims to define the invention more particularly and distinctly so as to overcome the technical rejections and define the invention patentably over the prior art.

The Claims Rejection Under 35 USC § 102

The newly amended claims have overcome the Examiners rejection of claims 1-4, 6, 9, and 10 under 35 U.S.C. 102(b) as being anticipated by Urnovitz. This reference describes a test strip made up of a "**solid support**", see column 6, line 59, and it is shown as a "solid "dip stick" structure", see column 6, line 61. The solid support test strip has specific "discrete areas", see FIG. 1., that the reagents "may" be in. This is very important in describing the patentably distinctness of the two devices. The reaction areas of the Urnovitz device **cannot** interact with each other. They are dependent on some other solution being introduced to complete the necessary **steps** of the reaction. The Smith patent has not such **limitations**. The device of Urnovitz cites **multiple steps** and requirements (i.e. incubations, etc.) to complete the analysis for the presence of an HIV antigen(s) in urine or other fluids. This device **also** requires the use of incubators, test plates, chambers, and treatment buffers (containing solid phase particles) to detect antigens for HIV. In contrast the invention of Smith employs a single lateral flow device or dry chemistry test device that requires only one step for the analysis of HIV antibodies in urine or other fluids. It **does not include** the use of incubators, test plates, chambers, treatment and buffers. The physical features of Smith are completely different (**novel**) from that of Urnovitz clearing the claims of Smith from any §102 rejections. For example, see Smith's specification pages 49-51. This describes a lateral flow device that is 5 mm by 70 mm in size where the chemical reaction between the HIV antibody in urine reacts with the reagents impregnated onto the lateral flow strip, wherein the reaction takes place within the matrix of the lateral medium. The reaction occur as the urine **migrates** from one area of the device to another interacting with the reagents, the

reagents and urine continue flowing another area and more interaction take place. The device of Urnovitz describes multiple reactions that take place on the solid support, buffers, chambers, etc., that occur on the surface of the discrete areas of the Urnovitz device. These **discrete areas** of Urnovitz do not move or interact with each other. The detection of HIV antibodies as taught by Smith occur within the matrix of the lateral flow strip or test pad itself. This novelty of the Smith device was not mentioned or taught by Urnovitz because it not possible using the teachings of Urnovitz. Again, the discrete areas of the Urnovitz test device where the reactions take place cannot migrate to another area for another reaction to take place. There is no mention by Urnovitz of using a lateral flow medium to transport fluid from one section of the test strip to another so that a reaction may take place or transferring the fluid through lateral flow to a test pad. This is patentably distinct and "novel" in structure and functionality over the Urnovitz device. Because of this and other reasons the Smith device is not limited to all of the requirements of the Urnovitz device.

The Examiner rejection to claims 1-4, 6, 9, and 10 in view of Urnovitz under 35 U.S.C. § 102 should be reversed because Urnovitz does not teach applicant's limitations as claimed, i.e., lateral flow device or dry chemistry test strip. Therefore, Urnovitz fails the first step of inquiry with respect to a 35 U.S.C. § 102 rejection anticipation reference. See *In re Spada*, 15 USPQ 2d 1655, 1656 (CAFC 1990) where the Court of Appeals For the Federal circuit stated, "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all elements of the elements of the claimed invention be described in a single reference." In addition, the Court stated, "Further, the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it." This Urnovitz reference does not because it fails to disclose a lateral flow device or the use of a dry chemistry test pad for the determination of HIV antibodies in urine or other fluids. The Urnovitz describes a system for the analysis of antigenic substances in urine or other fluids.

In addition there is no teaching by Urnovitz of **normalizing** urine sample for the accurate determination of the amount of HIV antibodies present. The Examiner cites "pretreating urine to normalize is well known in the art". The pretreatment steps as required by Urnovitz has nothing to do with the actual measurement of urinary concentration. These pretreatment steps where to remove **interfering substances**, see column 8, lines 49-68. Again, this has nothing to do with the actual measurement of urine creatinine, cystatin C or specific gravity to allowed the anti-HIV to be normalized to urinary concentration. In fact, Urnovitz claims that the Urnovitz assay is independent of the concentration because Urnovitz claims his device can work on concentrated and unconcentrated urines, see column 24, lines 16-59. Which is not scientifically valid in view of urine concentration directly related to HIV antibody concentration.

The device of Smith uses a "**new principle of operation**" in that the use of lateral flow and dry chemistry was not taught by the prior art and is absolutely novel in structure as compared to the prior art. The applicants invention solves a different problem than the reference, and such differences are cited in the claims, such as no required pretreatment of specimens prior to analysis, the use of a single device "one step" to determine the presence of HIV antibodies. See *In re Wright*, 6 USPQ 2d 1959 (1988). Since the Examiner's argument does not support a rejection of the newly amended claims under 35 U.S.C. 102(b), and because the invention of Smith recites numerous novel physical features that would clear any § 102 rejections the decision to reject the claims based on 35 U.S.C. § 102(b) should be reversed.

The Claims Rejection Under 35 USC § 103

Claim 7 was rejected under 35 U.S.C. § 103(a) as being anticipated by Urnovitz as applied to claims 6, 7, 9 and 10 in view of Huang, et al. The Urnovitz reference describes a method for measuring HIV antigens in urine or other fluids using a whole collection of parts to include a solid support mechanism with discrete areas of reaction that do not

interact with each other, chambers, incubators, buffers with sera for pretreatment of specimen and the Huang device which includes method for the measurement of HCG in urine using lateral flow. The devices or specifications of Urnovitz and Huang do not mention anywhere the use of normalization to insure test validity. In contrast the device(s) of the Smith invention employs completely different methodologies for lateral flow and dry chemistry testing of HIV antibodies. The method is one step. The device is not limited to the multiple steps of Urnovitz and has nothing to do with the measurement of HCG in urine.

The Examiner should reverse the rejection of claim 7 under 35 U.S.C. § 103(a) as being anticipated by Urnovitz as applied to claims 6, 7, 9 and 10 in view of Huang, et al. Because applicant's newly amended claims 6, 7, 9 and 10 recite novel physical features (i.e., it clears § 102). The novel physical distinctions of claims 6, 7, 9, and 10 are unobvious under § 103(a) for the following reasons. The present device produces **unexpected results** due to the inherent design and capability differences between the inventions. When the devices are juxtapose the results produced are unexpected. The present device is a single step method for the analysis of HIV antibodies in urine or other fluids effectively allowing **superior** results with reference to time, cost, and accuracy. The present device requires **no pretreatment** as the Urnovitz device does. Urnovitz is a complicated, multiple, and tedious method for the analysis of HIV antigens in urine or other fluids and is not an advancement in the art as the case with the Smith patent. The limitations of Urnovitz as mentioned and Huang do not allow for the **unsuggested** and **superior** capability if the present device. Without a showing in the Smith patent that a complicated device with multiple steps for the measurement of HIV antigens and / or HCG is required (which there is none) the rejection by the Examiner improper. The present device **omits elements** certain and critical elements of the Urnovitz and Huang device(s) namely the present art does not require solid support device with discrete zones of reaction, pretreatment buffers, chambers, incubators to name a few.. The present art by

not including these elements of the prior art is in fact more capable of producing a more **clinically significant** result for the presence of HIV antibodies in urine or other fluids therefore producing a **superior** functional device. The prior art of Urnovitz and Huang are **vague** and do not explain any of the present arts novel features. Urnovitz and Huang fail to teach or mention in any of their specifications or claims the important step of normalization of urine using endogenous steady state by-products of human metabolism. The Examiner has not presented a convincing line of reasoning as to why the claimed subject matter as a whole, including its differences over the prior art, would have been obvious. Neither Urnovitz nor Huang not teach the present art. The applicant's invention **solves a different problem** (detection of HIV antibodies in urine using a single step) that the reference cannot, and such a solution to the different problem is recited in the claims.

It appears to the applicant that the Examiner has made a **strained interpretation** of the reference that could only be made by hindsight. As the Courts have stated, "It is impermissible to use the claimed invention as an instruction manual to "template" or piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that one cannot use hindsight construction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." in re Fritch supra, 1784.

Thus the applicants submits that their invention clearly recites novel physical subject matter which distinguishes over any possible combination or use of Urnovitz in view of Huang.

The Newly Amended Novel Physical features of Claims 6, 7, 9, and 10 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The Reference Under § 103.

Again, Such hindsight reconstruction of an invention to support a rejection under 35 U.S.C. 103 is improper as clearly set forth by the Court of Appeals For the Federal Circuit in *In re Fritch*, 23 USPQ 2d 1780 at 1783-1784 (CAFC 1992) where it is stated,

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination" ..... "Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or `template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This Court has previously stated that `[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures of the prior art to deprecate the claimed invention'."

For these reasons, the Examiner's rejection of newly amended claims 6, 7, 9, and 10 under 35 U.S.C. § 103 should be reversed.

Again, the Examiner's rejection of amended claims 6, 7, 9, and 10 as obvious within the meaning of 35 U.S.C. § 103. over Urnovitz in view of Huang should be reversed. Applicant's invention of claims 6, 7, 9, and 10 are not obvious when compared to the prior art of Urnovitz in view of Huang because such prior art as a whole does not teach applicant's invention. Rather, some of the prior art teaches various aspects of detection of HIV antigens and HCG in urine which are in no manner even slightly similar to the present art. Furthermore, no suggestion is made by any of the prior inventors to combine any of these prior art elements to form applicants' device. For these reasons applicants are entitled to allowance of amended claims 6, 7, 9, and 10. Examiner to disprove the applicant's device the use of a rejection on this basis is improper and not legally defensible.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. **Under section 103**, teachings of references can be combined only if there is some suggestion or incentive to do so." In re Fritch, 23 USPQ 2d 1780, 1783 (CAFC 1992).

Applicants request reconsideration for the following reasons:

(1) There is no justification, Urnovitz or Huang, or any other prior art separate from applicants' disclosure, which suggests that these references be combined, much less be combined in the manner proposed.

(2) The proposed combination would not be physically possible or operative.

(3) Even if Urnovitz and Huang were to be combined in the manner proposed, the proposed combination would not show all of the novel physical features of claims 6, 7, 9 and 10.

(4) These novel physical features of claims 6, 7, 9 and 10 produce new and unexpected results and hence are unobvious and patentable over these references.

The prior art does not teach the present art or solves any problems of the prior art then why the rejection? 35 U.S.C. 103 **does not require** all of the elements of the prior art to be used in combination. Therefore, and in fact, if the Examiner uses any combination of the prior art and still not create the present art it in fact invalidates the Examiners argument.

That the suggestion to combine the references should not come from applicant was forcefully stated in Orthopedic Equipment Co. v. United States, 217 U.S.P.Q. 193, 199 (CAFC 1983):

"It is wrong to use the patent in suit [here the patent application] as a guide through the maze of prior art references, combining the right references in the right way to achieve the result of the claims in suit [here the claims pending]. Monday morning quarterbacking is quite improper when resolving the question of nonobviousness in a court of law [here the PTO]."

As was further stated in Uniroyal, Inc. v. Rudkin-Wiley Corp., 5 U.S.P.Q.2d 1434 (C.A.F.C. 1988), "[w]here prior-art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned fro the invention itself.... Something in the prior art must

suggest the desirability and thus the obviousness of making the combination," [Emphasis supplied.]

In line with these decisions, recently the Board stated in Ex parte Levengood, 28 U.S.P.Q.2d 1300 (P.T.O.B.A.&I. 1993):

"In order to establish a ***prima facie*** case of the obviousness, it is necessary for the examiner to present ***evidence***, preferable in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art ***would have been led*** to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. ...That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can ***reconstruct*** and/or explain the theoretical mechanism of an invention by mean of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.... Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a ***prima facie*** case of obviousness only by showing some objective teaching in either prior art, or knowledge generally available to one of ordinary skill in the art, that 'would lead' that individual 'to combine the relevant teachings of the references.' ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the ***motivating force*** which would impel one skilled in the art to do what the ***applicant has done."***

In the present case, there is nor reason to support the proposed combination of Urnovitz and Huang. However the fact that both references teach a device that is supposed to be used in the detection of HIV antigens and HCG in urine is not sufficient

to **gratuitously and selectively** substitute parts of one reference for a part of another references in order to attempt to meet applicants' novel claimed invention.

Applicant therefore submits that combining Urnovitz and Huang is not legally justified and is therefore improper. The applicants respectfully request that the claims 6, 7, 9 and 10 be reversed and if the Examiner continues to reject the claims upon any combination of references, that the Examiner include an explanation, in accordance with M.P.E.P. § 706.02, Ex parte Clapp, 27 U.S.P.Q. 972 (P.O.B.A. 1985), and Ex parte Levengood, supra, a "factual basis to support the Examiner's conclusion that it would have been obvious" to make the combination.

Even if Urnovitz and Huang Were To Be Combined In The Manner Proposed, The Proposed Combination Would Not Show All Of The Novel Physical Features Of The Claims

However, even if the combination of Urnovitz and Huang were legally justified, amended claims 6, 7, 9 and 10 would still have novel (and nonobvious) physical features over the proposed combination. In other words, applicant's invention, as defined by amended claims 6, 7, 9, and 10, comprises much more than merely substituting a plurality of elements to try to create the Smith invention.

The Novel Physical Features Of Amended Claims 6, 7, 9 and 10 Produce New And Unexpected Results And Hence Are Unobvious And Patentable Over The References Under § 103.

For this reason, the Examiner's rejection of amended claims 6, 7, 9, and 10 under 35 U.S.C. § 103 should be reversed.

Conclusion

For all o the above reasons, applicant submits that the specification and claims are now in proper form, and that the claims all define patentably over the prior art. Therefore the applicant submits that this application is now in condition for allowance, which action is respectfully solicited.

Conditional Request For Constructive Assistance

Applicants have amended the specification and claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason this application is not believed to be in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to M.P.E.P. § 107.03(d) and § 707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very Respectfully Submitted,

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signed Jack V. Smith